Proposal Title	Specialty Medication Prior Authorizations (R020)
Health Plan Affected	Defined Benefit Retiree Plan
Proposed Effective Date	January 1st, 2022
Reviewed By	Retiree Health Plan Advisory Board
Review Date	September 9, 2021

Contents

1) Background

Specialty Medications

Specialty medications are typically highly complex, high-cost, or high-touch drugs that often require very specialized storage protocols or must be administered in a very specific manner. Specialty drugs:[1,2]

- May be prescribed for a person with a complex or chronic medical condition, defined as a physical, behavioral, or developmental condition that may have no known cure, is progressive, and/or is debilitating or fatal if left untreated or under-treated;
- Treat rare or orphan disease[3] indications;
- Require additional patient education, adherence, and support beyond traditional dispensing activities;
- Are oral, injectable, inhalable, or infusible drugs;
- Have a high monthly cost (*e.g.*, more than $1,000 for a 30-day supply)[4,5]
- Have unique storage or shipment requirements, such as refrigeration; and
- Are not typically stocked at retail pharmacies.

Many specialty medications are prescribed to treat chronic conditions, meaning that utilizers are likely to use that medication for a long time.

Specialty Medications as a Cost Driver

Specialty medications are one of the largest rising cost drivers in pharmaceutical spend. In the United States in 2008, specialty medications accounted for just over 20% of pharmaceutical spend; by 2023, that percentage is expected to climb to over 50%.[6]

In the AlaskaCare Defined Benefit Retiree Health Plan (Plan), specialty medication use has grown along with its percentage of overall cost. In 2014, specialty medications accounted for 0.7% of total prescriptions and 19% of total Plan pharmacy cost (or $33.5M out of $176.7M).[7] In 2020, specialty costs for less than 1% of prescriptions (associated with 3.7% of members utilizing the prescription drug plan, or 3.0% of total Plan members) made up 37%, or $110 million of the total Plan prescription drug spend. The

[1] Pharmaceutical Care Management Association. "What is a Specialty Drug?" https://www.pcmanet.org/pcma-cardstack/what-is-a-specialty-drug/

[2] See Attachment B: Characteristics of specialty medications, OptumRx Specialty Pharmacy Drug List, July 1, 2021, page 2.

[3] Affecting fewer than 200,000 people

[4] See Attachment B: Characteristics of specialty medications, OptumRx Specialty Pharmacy Drug List, July 1, 2021, page 2.

[5] Medicare defines drugs with a 30-day equivalent negotiated price of $670 or more as a specialty drug. https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2021%20mtm%20and%20specialty%20thresholds%20final%20part%20d%20bidding%2005.22.2020_8.pdf

[6] The Global Use of Medicine in 2019 and Outlook to 2023: Forecasts and Areas to Watch. IQVIA Institute. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023.pdf?_=1626801058214

[7] 2014 4th Quarter AlaskaCare Retiree Health Plan Report, pages 32-33.

Plan's costs for specialty medications increased $21 million from 2019 to 2020 (24%), due to increased prescriptions and utilization of higher cost medications.[8]

Specialty Medication Spend in the AlaskaCare Retiree Plan

Though specialty drug claims account for less than 1% of all AlaskaCare retiree Plan pharmacy claims in 2020, the $110 million in Plan costs associated with those prescriptions totaled 37% of the total pharmacy spend. In 2020:[9]

- 60,677 AlaskaCare retiree Plan members filled prescriptions through the Plan's prescription drug benefit.
- 2,272 individuals (3.7% of all utilizers) filled 10,923 prescriptions for specialty medications.
- Those specialty prescriptions represent less than 1% of the overall 1,380,472 total prescriptions filled by all utilizers.

These medications can have high costs per utilizer, as evidenced by table 1 below.

Table 1. AlaskaCare Top 5 Specialty Medications for Chronic Conditions, 2020[10]

Specialty Drug	Average Cost per 30 Day Supply per Individual Utilizer	Average Cost Annually per Individual Utilizer	Total Utilizers in 2020	Average Annual Total Spend*
Humira Pen	$9,570	$114,841	166	$19,063,606
Xeljanz XR	$9,476	$113,715	74	$8,414,910
Enbrel Sureclick	$10,017	$120,213	59	$7,092,567
Jakafi	$13,369	$160,439	16	$2,567,024
Revlimid	$16,061	$192,743	60	$11,564,580

**Assumes utilizers used the medication for the duration of 2020*

AlaskaCare Retiree Plan Coverage Provisions

The Plan provides coverage for outpatient prescription drugs for the treatment of an illness, disease, or injury if dispensed upon prescription of a provider acting within the scope of their license.[11] *Section 4.5 Medical Necessity* under the Prescription Drugs section of the PIan states:

> "To be covered under the plan prescription drugs must be medically necessary and clinically appropriate. This provision does not require the use of generic drugs.
>
> The plan will cover some drugs only if prescribed for certain uses, or durations. Certain medications have specific dispensing limitation for quantity, age, gender and maximum dose. Determination of medical necessity will be based on recommendations by the federal Food and Drug Administration (FDA), combined with the pharmacy benefit managers standard coverage policies designed to ensure the medication prescribed is safe and effective. For this reason, some prescription medications may

[8] See Attachment A: OptumRx Presentation, *Retiree Plan Specialty Prior Authorization Opportunity*. June 18, 2021, page 5.
[9] Ibid, page 8.
[10] Ibid, page 4.
[11] AlaskaCare Retiree Insurance Information Booklet, January 2021. *Section 4. Prescription Drugs.* http://doa.alaska.gov/drb/pdf/ghlb/retiree/AlaskaCareDBRetireeBooklet2021.pdf

be subject to prior authorization to determine that the requested prescription drug is medically necessary.

The prior authorization ensures you are getting the most appropriate care and will occur in the best setting. This helps produce improved health outcomes and lower health care costs by reducing duplication, waste, and unnecessary treatments."[12]

Prior authorization for prescription drugs is a pharmacy management process that reviews certain medications against clinical, evidence-based standards including those established by the FDA to promote safe and effective use of those medications. Similar to how most medical plans (including the AlaskaCare Defined Benefit Retiree Health Plan) require precertification for certain intensive, complex, and high-cost medical services, prior authorization is a common tool used by pharmacy plans to review dispensation of many different types of medications, including specialty medications.

The Division of Retirement and Benefits (Division) contracts with a Pharmacy Benefit Manager (PBM) – currently OptumRx – to process AlaskaCare prescription drug claims in accordance with the Plan and to apply any appropriate pharmacy management processes.

The prior authorization pharmacy management process is a critical tool for evaluating if the person utilizing a specialty medication meets the medical necessity guidelines outlined by the Plan and established by the FDA and other entities. Without the prior authorization process, the PBM does not have an alternative means to receive and review the information necessary to ensure the patient receiving the medication meets these criteria, including basic diagnostic information.

Currently the Plan does not have this prior authorization process in place for specialty medications. As the use of, and indications for, specialty medications increase, the need for the prior authorization process is becoming acute.

2) Objectives

a) Promote safe and effective use of medications in accordance with evidence-based clinical standards.
b) Employ prudent pharmacy management strategies to curtail unnecessary or unsafe utilization of high-cost medications.

3) Summary of Proposed Change

Prior authorization requires prescribers to provide patient-specific medication treatment information for review prior to approval and dispensing to the patient. This review ensures that a prescription drug is medically necessary, appropriately prescribed, meets FDA and other clinical guidelines for the condition being treated, and is therefore eligible for coverage by the Plan. By following clinical standards with use of evidence-based guideline criteria, the prior authorization process promotes safe and effective use of these medications.

[12] AlaskaCare Retiree Insurance Information Booklet, January 2021. *Section 4.5 Medical Necessity.* http://doa.alaska.gov/drb/pdf/ghlb/retiree/AlaskaCareDBRetireeBooklet2021.pdf

The Division proposes implementing prior authorization requirements for specialty medications. To do so, the Plan would adopt OptumRx's specialty prior authorization program. Under the proposed program, before the Plan would provide coverage for certain specialty medications, OptumRx must receive and approve a prior authorization for the medication.

Prior Authorization Process

Providers may submit prior authorization requests electronically, over the phone, or by mail. The prior authorization process is designed with expediency in mind.

Real Time: When appropriate, electronically submitted prior authorizations may be approved in real time through an automated system. Many providers (both in and out of network) have access to OptumRx's PreCheck MyScript tool, an integrated add-on to commonly used Electronic Medical Record (EMR) systems that provides real-time, patient specific drug cost and coverage details. Use of PreCheck MyScript can help ensure that prior authorizations are submitted and approved before the member initiates a prescription fill.

72 Hours: OptumRx processes and provides notice of prior authorization determinations within 72 hours. Initial determination notices may be provided verbally to expedite processing of the prescription, and a written follow-up notice will be mailed within three calendar days. Members can also monitor the status of a prior authorization request on the OptumRx secure portal or mobile app.

24 Hours: Expedited requests are processed, and determination notice is provided within 24 hours.

Because health plans commonly include prior authorization requirements for specialty medications, most clinicians are familiar with the process and are prepared to submit a prior authorization request before the member fills the prescription.

If a required prior authorization is not submitted prior to the member attempting to fill the prescription, when the pharmacy processes the prescription, they will receive a message at the point-of-sale indicating that prior authorization is required. The pharmacy typically notifies the prescribing physician, who is then responsible for submitting the prior authorization request and any associated required additional information.

One the prior authorization has been submitted, OptumRx will review the prescription against clinical criteria specific to the drug and to the member's condition to ensure safe and effective use of the medication. Members will have the ability to access the clinical criteria specific to their specialty medication via the OptumRx online member portal, or by calling OptumRx customer service.

- If the prior authorization request meets the clinical criteria, it will be approved, and the prescription may be filled.
- If more information is needed, OptumRx will reach out to the prescribing provider.
- If the information provided does not meet clinical criteria, coverage for the prescription will be denied, and information regarding the specific clinical criteria that was not met will be provided to the member.
    - The member may appeal this decision through the AlaskaCare appeals process, or they may work with their prescriber to obtain a different prescription.
    - The member's prescriber may provide additional clinical information to OptumRx to support use of the medication by the member, or they may request a peer-to-peer

discussion with an OptumRx clinical pharmacist to discuss the member's individual condition and circumstances.

Prior authorization approvals are typically valid for 3-36 months, depending on the medication. OptumRx identifies approved prior authorizations expiring within 30 days and will proactively reach out to the prescriber to request any information needed for reauthorization.

If members are unsure if their current medication or any new prescriptions require a prior authorization, they may call OptumRx, consult the Plan's formulary[13] (list of prescribed medications), or review the current OptumRx Specialty Pharmacy Drug List (see attachment B) to determine if their drug is subject to prior authorization.

Development of Prior Authorization Clinical Criteria

Every PBM has a process for reviewing and aggregating clinical guidelines to establish the clinical criteria used to evaluate prior authorization requests. This proposal contemplates the use of OptumRx's clinical criteria. However, if the plan transitions to a different PBM in the future, that PBM's clinical criteria would be used to evaluate any prior authorizations in effect at that time.

At OptumRx, prior authorization criteria are reviewed and approved by the OptumRx Pharmacy & Therapeutics (P&T) Committee. The P&T Committee is an independent, multi-specialty and nationally represented group of physicians and pharmacists. The P&T Committee evaluates medications based on scientific evidence to find their place in therapy. Quarterly meetings are held to evaluate, review, and make clinical recommendations. Industry, clinical, and company standards govern the P&T Committee's review, consideration, and recommendation processes. The committee considers:

- U.S. Food and Drug Administration (FDA) approved indications
- Manufacturer's package labeling instructions
- Well-accepted and/or published clinical recommendations (ex: American Hospital Formulary Service Drug Information; DRUGDEX; National Comprehensive Cancer Network Drugs and Biologics Compendium; Clinical Pharmacology; major peer reviewed medical journals such as the American Journal of Medicine)

Based on this information, the P&T Committee evaluates whether a drug has a unique therapeutic benefit, comparable safety and efficacy, or whether risk of harm outweighs the benefits. The P&T Committee complies with national quality standards including those provided by the Centers for Medicare & Medicaid Services (CMS), the National Committee for Quality Assurance (NCQA), and the Utilization Review Accreditation Commission (URAC®). After thorough clinical review of prior authorization guidelines is complete, the P&T Committee approves the utilization management criteria.

Actuarial Impact | Neutral
Financial Impact | Annual Cost Reduction ~$7.7M
Member Impact | Low
Operational Impact (DRB)| Minimal
Operational Impact (TPA) | Minimal

[13] AlaskaCare formularies are available online: http://doa.alaska.gov/drb/alaskacare/optumrx.html

4) Impacts

Actuarial Impact | Neutral

This proposal will not result in a change to members' cost share for their covered prescriptions, nor will it remove coverage for any class or drug covered by the plan. Therefore, implementing prior authorizations for specialty medications will not have an impact on the actuarial value of the Plan.[14]

Financial Impact | Annual Cost Reduction ~$7.7M

Cost Saving Potential

Prior authorization is a core component of prudent pharmacy plan management. Medications requiring prior authorization typically have limited FDA-approved uses, are used for conditions that require special diagnostic confirmation, or have a high potential to be prescribed for off-label uses where appropriateness and efficacy are not well established. If left unmanaged without requiring prior authorization, these medications can significantly increase plan costs.

Prior authorizations review medications to ensure safe and effective use. Though cost of the drug is not one of the criteria used to review use of a medication during the prior authorization process, implementation of the prior authorization program is anticipated to bring annual incidental savings to the plan. Plan savings associated with prior authorizations typically fall into four general categories:[15]

1. Increased Drug Rebates: The Plan will be eligible to receive increased drug rebates that are provided to plans that adopt prior authorizations. The more favorable rebates are provided regardless of the outcome of any prior authorization requests.
2. Drug Not Approved: Some prior authorization requests are not approved because the drug is not appropriate for the member's condition, or because it has been prescribed in a manner contrary to evidence-based guidelines. For example, Xyrem is an orphan drug that is FDA approved to treat narcolepsy but is not covered for chronic fatigue syndrome or fibromyalgia. A prior authorization review would ensure that it has been prescribed to treat an appropriate condition. If an alternative prescription is not written, the cost of the drug is considered savings to the Plan.
3. Alternative Drug Prescribed: Some prior authorization requests result in the prescribing physician writing a prescription for an alternative medication. Alternative drugs are not always specialty medications and may not necessarily require a prior authorization. If a prior authorization request results in dispensation of an alternative drug, the difference between the cost of the original medication and the cost of the alternative medication is considered savings to the Plan.
4. Prescription Abandoned: Some prior authorization requests are abandoned by the provider or by the member. Examples of abandoned outcomes include the member switching to a non-medication treatment option (*e.g.*, light therapy for psoriasis), the doctor not responding to the prior authorization request from the pharmacy, or the member not taking any action to pursue the prior authorization or fill the prescription. In these instances, the cost of the drug associated with the abandoned prior authorization is considered savings to the plan.

[14] *OptumRx Retiree Plan Specialty Prior Authorization Program – Focus on Actuarial and Financial Impact for the Retiree Plan - UPDATED,* Segal memo dated August 27, 2021. (Attachment D).
[15] OptumRx Presentation, Retiree Plan Specialty Prior Authorization Opportunity. June 18, 2021.

Projected Annual Cost Impact

The financial impact analysis is based on initial savings estimates provided by OptumRx, which were further refined by Segal to account for prescribing and utilization patterns specific to the Plan.

Based on Segal's preliminary retiree medical and pharmacy claims projection of $617,000,000 for 2022, the anticipated fiscal impact of this change in 2022 is estimated to be an overall reduction in pharmacy costs of approximately $7,700,000 (or 1.2% of total projected costs).[16]

Implementing a prior authorization program for specialty medications is anticipated to have an impact on prescription drug claims costs, manufacturer drug rebates, and federal subsidies provided to the Plan through the AlaskaCare enhanced Employer Group Waiver Program (EGWP) Medicare Part D prescription drug plan. The EGWP subsides are anticipated to reduce by approximately $2,000,000, but this reduction will be more than offset by the savings associated with claims costs and increased drug rebates.

The projected claims savings are largely due to alternative, more clinically appropriate drugs being prescribed, though some reviews may result in no medications being prescribed. Assuming that over 90% of retirees taking medications on the prior authorization drug list will be approved, the anticipated claims savings for 2022 are $4,500,000.

Adding prior authorization requirements enables the Plan to access more advantageous drug manufacturer rebate terms. Increased drug rebates associated with the implementation of specialty mediation prior authorizations are available to the Plan regardless of whether or not the prior authorization review results in an alternative medication being dispensed. The anticipated rebate increases for 2022 are expected to be $5,200,000.

Table 2. Projected 2022 Savings Detail[17]

Financial Impact	Non-EGWP	EGWP	Total
2022 Claims Savings	$1,400,000	$3,100,000	$4,500,000
2022 Rebates Changes	$3,600,000	$1,600,000	$5,200,000
2022 EGWP Changes	N/A	($2,000,000)	($2,000,000)
Total Savings	**$5,000,000**	**$2,700,000**	**$7,700,000**

Projected Long-Term Cost Impact

The annual cost decrease associated with the proposed prior authorizations may have long-term impacts to the healthcare Actuarial Accrued Liability (AAL)[18] and to the Additional State Contributions (ASC)[19] associated with the Plan.

To estimate the long-term financial impacts of this proposal, Buck considered the estimated 2022 decreases and projected future annual cost decreases using the June 30, 2020 valuation assumptions. Based on these estimates, the AAL would have decreased by approximately $100.8 million, and the ASC

[16] *OptumRx Retiree Plan Specialty Prior Authorization Program – Focus on Actuarial and Financial Impact for the Retiree Plan - UPDATED,* Segal memo dated August 27, 2021. (Attachment D).
[17] Ibid.
[18] AAL: The excess of the present value of a pension fund's total liability for future benefits and fund expenses over the present value of future normal costs for those benefits.
[19] Employer contributions to retirement payments were capped in FY08. Since then, the state makes additional assistance contributions to help cover the accrued unfunded liability associated with participating employers.

for Fiscal Year (FY) 2023 would have decreased by approximately $1.1 million if these changes had been reflected in the June 30, 2020 valuations. [20]

The ASC provides payment assistance to participating employers' Actuarially Determined Contribution (ADC). The ADC is determined by adding the "Normal Cost"[21] to the amount needed to offset the amortization of any existing unfunded accrued liability over a period of 25 years.

The illustrative decrease to the FY23 ASC is associated with the Normal Cost only. The current overfunded status[22] of the retiree health care liabilities has eliminated the immediate need for amortization payments to offset any health care unfunded liability. It is important to note the that long-term funded status of the trusts is subject to change in response to market volatility and many other factors.

If the retiree health care liabilities were not overfunded, in accordance with the Alaska Retirement Management Board's (ARMB) current funding policy, the total illustrative decrease in the FY23 ASC would be approximately $7.6 million.[23]

Member Impact | Low

Implementation of prior authorizations for specialty medications will impact a small portion of Plan members. As previously discussed, out of 60,677 members who filled prescription medications in 2020, only 3.7%, or 2,272 individuals, filled prescriptions for specialty medications that would be subject to prior authorization. The Division anticipates the majority of members will continue with their current therapy. Some members may not receive an approval for the prior authorization request for their medication, and those members will need to transition to a different medication or work with their prescriber to provide necessary clinical information to support use of the originally requested medication.

Prescribers will need to complete the prior authorization process for members newly prescribed certain specialty medications after January 1, 2022. Members may contact OptumRx, review individualized information about their prescriptions on the OptumRx.com member portal, or consult the current OptumRx Specialty Pharmacy Drug List (see attachment B) to determine if any of their current medications are specialty medications that are subject to prior authorization. Medications on the list that require a prior authorization are indicated with a "PA" designation after the drug name.

Members who are currently utilizing specialty medications will be notified by mail 60 days in advance of prior authorizations going into effect that a medication they are using will be subject to prior authorization. These members will be advised to speak with their provider, so that the provider is aware

[20] *Revised Impact of Potential Change in Prior Authorization of Specialty Medications for AlaskaCare Retiree Health Plan,* Buck, August 27, 2021.

[21] The normal cost represents the present value of benefits earned by active employees during the current year. The employer normal cost equals the total normal cost of the plan reduced by employee contributions.

[22] Due in part to the savings realized as a result of the 2019 implementation of the enhanced Employer Group Waiver Program (EGWP) group Medicare Part D prescription drug program, the retiree health care liabilities are currently overfunded. The Division's 2020 draft Actuarial Valuation Reports for the Public Employees' Retirement System (PERS) and the Teachers' Retirement System (TRS) indicate that the PERS actuarial funded ratio is 113.5% and the TRS actuarial funded ratio is 121.4%.

[23] *Revised Impact of Potential Change in Prior Authorization of Specialty Medications for AlaskaCare Retiree Health Plan,* Buck, August 27, 2021.

of the need to submit a prior authorization. Their provider will then initiate the prior authorization through the process described above in section 3.

Members who receive a new prescription for a specialty medication after prior authorizations are implemented will need to work with their prescriber to obtain the relevant prior authorization.

Because most health plans include a requirement for prior authorization for specialty medications, most providers are familiar with the process and are prepared to submit the necessary request and documentation before the member attempts to fill their prescription. In most cases, prior authorization is a process that occurs between the provider and OptumRx, and the member should not have to be heavily involved in the process.

There is no change to coverage for prescription medications that are prescribed under the terms outlined in the Plan booklet. The plan will continue to cover medically necessary and clinically appropriate prescription drugs, and there will be no change to the amount retirees pay for their medications.

Operational Impact (DRB)| Minimal

To implement this change, the Division will need work with OptumRx to ensure that the prior authorization process is correctly implemented, including auditing and verifying the set-up, creating and executing a member and provider communication campaign, and preparing both the Division and OptumRx's member services centers to assist members with questions related to prior authorizations.

Operational Impact (TPA) | Minimal

Prior authorizations for specialty medications are a common plan feature and are included in nearly all commercial and self-insured plans administered by OptumRx. OptumRx has a robust prior authorization department that is already prepared to process any requests, and their member services staff are well versed in the program.

5) Proposal Recommendations

DRB Recommendation

The Division of Retirement and Benefits recommends implementation of this proposal, effective January 1, 2022.

RHPAB Board Recommendation

Insert the RHPAB recommendation here when final along with any appropriate comments.

Description	Date
Reviewed by Modernization Subcommittee	06/18/2021, 07/28/2021, 08/19/2021
Reviewed by RHPAB	11/05/2020, 08/05/2021, 09/09/2021

Documents attached include:

Attachment	Document Name
A	OptumRx Presentation, *Retiree Plan Specialty Prior Authorization Opportunity*, June 18, 2021.
B	OptumRx Specialty Pharmacy Drug List, July 1, 2021

C	OptumRx Presentation, *Specialty Prior Authorization*, July 28, 2021.
D	*OptumRx Retiree Plan Specialty Prior Authorization Program – Focus on Actuarial and Financial Impact for the Retiree Plan - UPDATED,* Segal, August 27, 2021
E	*Revised Impact of Potential Change in Prior Authorization of Specialty Medications for AlaskaCare Retiree Health Plan,* Buck, August 27, 2021.